Message

From: Schappelle, Seema [Schappelle.Seema@epa.gov]
Sent: 3/16/2017 11:56:26 PM
To: Babich, Michael [MBabich@cpsc.gov]
CC: Barone, Stan [Barone.Stan@epa.gov]; Wooge, William [Wooge.William@epa.gov]
Subject: RE: Request for information on national EDC regulatory frameworks

Thank you!

Seema.

From: Babich, Michael [mailto:MBabich@cpsc.gov]
Sent: Thursday, March 16, 2017 5:28 PM
To: Schappelle, Seema <Schappelle.Seema@epa.gov>
Cc: Barone, Stan <Barone.Stan@epa.gov>; Wooge, William <Wooge.William@epa.gov>
Subject: RE: Request for information on national EDC regulatory frameworks

Dr. Schappelle,

Below are the Consumer Product Safety Commission's (CPSC) responses to the UN Environment's questions regarding endocrine disruptors. Most of the questions do not apply directly to CPSC, which does not have jurisdiction over pesticides, drinking water, drugs, or cosmetics, except for packing of drugs and cosmetics.

CPSC is an independent regulatory agency with jurisdiction over products used in and around the home, schools, and recreational settings, except products regulated by other federal agencies, such as food, drugs, cosmetics, pesticides, and automobiles. We do, however, have responsibility for child-resistant packaging of drugs, cosmetics, and household chemicals. Our regulatory authority over chemical hazards is primarily from the Consumer Product Safety Act and the Federal Hazardous Substances Act. Although we do not administer TSCA, our overall scheme for assessing and regulating chemical hazards is generally similar. Unlike pesticides and drugs, however, we do not have pre-market approval of chemicals or products.

Questions:

1) How are endocrine disrupting properties of industrial chemicals considered during the risk assessment and management under the reformed TSCA?

The CPSC considers chronic hazards from chemicals, including endocrine disruptors, under the Federal Hazardous Substances Act (FHSA). The FHSA is risk-based. We consider both hazard and risk in evaluating chemical hazards. Our risk assessment approach is described in our Chronic Hazard Guidelines (https://www.cpsc.gov/s3fs-public/pdfs/blk_pdf_chronichazardguidelines.pdf). The guidelines specifically address cancer, neurotoxicity, and reproductive/developmental toxicity, although the same principles apply to all chronic health endpoints. We generally classify chronic hazards by the relevant health endpoint. For example, we view certain phthalates as reproductive or developmental toxicants, even though they may act though an endocrine disrupting mechanism (https://www.cpsc.gov/chap).

2) At which steps of regulatory processes for pesticides are different stakeholders, such as producers or the general public, involved (e.g. through a public commenting process) and how are these stakeholders involved (e.g. do they have the possibility to comment on drafts etc.)?

The U.S. Environmental Protection Agency has jurisdiction for pesticides.

Although CPSC does not regulate pesticides, we regulate consumer products that may contain chemical ingredients. Stakeholders may be involved at several stages. CPSC regulations generally require public comment periods after issuing an Advance Notice of Proposed Rulemaking (ANPR) and Notice of Proposed

Rulemaking (NPR), before a final rule is issued. The Commission has the option of holding public hearings during the rulemaking process. CPSC is subject to open meetings requirements. The CPSC staff briefs the Commission (composed of 5 Commissioners) in public meetings. The staff is generally amenable to meetings with stakeholders. All meetings with non-governmental organizations must be open to the public, with certain exceptions, such as to protect proprietary information.

3) At which steps of regulatory processes for drinking water contaminants are different stakeholders, such as industry or the general public, involved (e.g. through a public commenting process) and how are these stakeholders involved (e.g. do they have the possibility to comment on drafts etc.)?

The U.S. Environmental Protection Agency generally has jurisdiction over drinking water contaminants.

4) How are food contact materials (FCMs) assessed for endocrine disrupting properties? What are the criteria for the identification of EDCs and what are the corresponding data requirements?

The U.S. Food and Drug Administration has jurisdiction over cosmetics, drugs, and food contact materials.

5) How are cosmetic ingredients assessed for endocrine disrupting properties? What are the criteria for the identification of EDCs and what are the corresponding data requirements?

The U.S. Food and Drug Administration has jurisdiction over cosmetics, drugs, and food contact materials.

6) How are drugs assessed for (unintended) endocrine disrupting properties? What are the criteria for the identification of EDCs and what are the corresponding data requirements?

The U.S. Food and Drug Administration has jurisdiction over cosmetics, drugs, and food contact materials.

7) How are efforts regarding the assessment and regulation of EDCs coordinated between different governmental agencies in the United States?

CPSC coordinates with other agencies in several ways. We have regular interagency meetings with the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) to discuss topics of common interest and to coordinate our activities. We are part of a government-wide task force (President's Task Force on Children's Environmental Health), which focuses on children's health. We are statutory members of the National Toxicology Program (NTP), the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM), and the EPA Interagency Testing Committee. We participate in many other interagency committees on various topics. We collaborate with a number of federal agencies through Interagency Agreements and Memoranda of Understanding (MOUs) for conducting research and coordinating activities. Most federal agency regulations are subject to interagency review. In some cases, such as the new TSCA, there are requirements for agencies to consult one another on new regulations.

Please feel free to contact me with any additional questions.

Best regards,

Mike Babich

Michael A. Babich, PhD, Director
Division of Toxicology & Risk Assessment
Directorate for Health Sciences
U.S. Consumer Product Safety Commission
5 Research Place
Rockville, MD 20850
301-987-2606

From: Schappelle, Seema
Sent: Friday, February 24, 2017 8:07 PM
To: 'sfitzpat@oc.fda.gov' <sfitzpat@oc.fda.gov>; 'mbabich@cpsc.gov' <mbabich@cpsc.gov>

Cc: Barone, Stan <Barone.Stan@epa.gov>; Wooge, William <Wooge.William@epa.gov>
Subject: FW: Request for information on national EDC regulatory frameworks

Hi Drs. Fitzpatrick and Babich,
I'm writing from EPA's Endocrine Disruptor Screening Program (EDSP). Jacqueline Alvarez from UNEP has posed the following questions regarding endocrine disruptors and we are preparing responses within two weeks. I'd like to ask for help from your organizations in preparing responses, especially regarding questions 4-7. Can you recommend a POC in your group that can help?

Thanks,
Seema Schappelle, Ph.D.
Director, Exposure Assessment Coordination and Policy Division
Office of Science Coordination and Policy
Office of Chemical Safety and Pollution Prevention, U.S. EPA
ph. 202.564.8006

Dear Katherine P. Weber,

We are writing to ask you for your kind assistance in collecting information regarding the national regulatory frameworks and policy initiatives on endocrine disrupting chemicals (EDCs) in the United States.

In response to the Resolution on EDCs agreed upon at the fourth session of the International Conference on Chemicals Management (ICCM 4, held in Geneva, from 28 September to 8 October 2015), UN Environment is working on the preparation of a series of overview reports regarding the environmental exposure and effects of EDCs, as well as a compilation of existing regulatory frameworks and policy initiatives.

The overview report on existing national, regional and global regulatory frameworks and policy initiatives aims to summarize the characteristics of existing initiatives including scope, criteria utilized, data needs and relevant processes.

We are interested in the current situation in your country and we have some specific questions following our initial review of available information. We would appreciate your time in clarifying these open points and we kindly request your help in answering the questions below by **February 19, 2017**.

If you have any questions or we could provide additional information about this request, please do not hesitate to contact us.

Questions:

1) How are endocrine disrupting properties of industrial chemicals considered during the risk assessment and management under the reformed TSCA?

2) At which steps of regulatory processes for pesticides are different stakeholders, such as producers or the general public, involved (e.g. through a public commenting process) and how are these stakeholders involved (e.g. do they have the possibility to comment on drafts etc.)?

3) At which steps of regulatory processes for drinking water contaminants are different stakeholders, such as industry or the general public, involved (e.g. through a public commenting process) and how are these stakeholders involved (e.g. do they have the possibility to comment on drafts etc.)?

4) How are food contact materials (FCMs) assessed for endocrine disrupting properties? What are the criteria for the identification of EDCs and what are the corresponding data requirements?

5) How are cosmetic ingredients assessed for endocrine disrupting properties? What are the criteria for the identification of EDCs and what are the corresponding data requirements?

6) How are drugs assessed for (unintended) endocrine disrupting properties? What are the criteria for the identification of EDCs and what are the corresponding data requirements?

7) How are efforts regarding the assessment and regulation of EDCs coordinated between different governmental agencies in the United States?

We welcome attachments with any document you consider relevant.

We thank you in advance for any information provided and send you our best regards,

Victor Estellano

Science and Risk Unit
Chemicals and Waste Branch, Economy Division
UN Environment

Tel: +41(0)229178735

On behalf of

Jacqueline Alvarez
Science and Risk Unit Leader
Chemicals and Waste Branch, Economy Division
UN Environment
International Environment House 1 (MIE1)
11-13 Chemin des Anémones
CH - 1219 Châtelaine
Geneva, Switzerland
Tel: +41 22 917 8350
Fax: +41 22 797 3460
E-mail: jacqueline.alvarez@unep.org
Skype ID: Jacqueline.alvarez.mourelle

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